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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/503,421	02/14/00	SCHWAEBLE	W 3523 P 004

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MONIQUE A MORNEAULT ESG
WALLENSTEIN & WAGNER LTD
311 SOUTH WACKER DRIVE
53RD FLOOR
CHICAGO IL 60606-6604

EXAMINER

ROMEO, D

ART UNIT	PAPER NUMBER
1647	9

DATE MAILED: 06/12/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No. 09/503,421	Applicant(s) Schwaeble
Examiner David Romeo	Art Unit 1647

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on 29 May 2001

2a) This action is FINAL. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) Claim(s) 1-10 is/are pending in the application.

4a) Of the above, claim(s) 1-9 is/are withdrawn from consideration.

5) Claim(s) _____ is/are allowed.

6) Claim(s) 10 is/are rejected.

7) Claim(s) _____ is/are objected to.

8) Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on _____ is/are objected to by the Examiner.

11) The proposed drawing correction filed on _____ is: a) approved b) disapproved.

12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13) Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) All b) Some* c) None of:

1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. _____.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) Notice of References Cited (PTO-892)

16) Notice of Draftsperson's Patent Drawing Review (PTO-948)

17) Information Disclosure Statement(s) (PTO-1449) Paper No(s). 6

18) Interview Summary (PTO-413) Paper No(s). _____

19) Notice of Informal Patent Application (PTO-152)

20) Other: _____

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DETAILED ACTION

1. Applicant's election without traverse of group IV, claim 10, and the species SEQ ID NO: 1 in Paper No. 8 is acknowledged.

2. Upon further consideration the requirement to elect a single disclosed species of SEQ ID NO: 1, 2, or 3 for prosecution on the merits is withdrawn.

3. Claims 1-9 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in Paper No. 8.

4. Upon further consideration the requirement to rewrite the claims prior to examination is withdrawn. The preliminary amendment filed concurrently with the instant application has been entered.

5. The abstract of the disclosure is objected to because the first page of an international application published under the Patent Cooperation Treaty (PCT) is not acceptable as an abstract in a U.S. patent application. An abstract on a separate sheet is required.

15 Correction is required. See MPEP § 608.01(b).

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Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

5 (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Krumdieck (a9)¹ in view of Stuart (1996, cited by Applicants).

Krumdieck teaches that when excessively activated or misdirected, complement-mediated inflammation can result in damage to host tissues. For example, complement-mediated inflammation has been demonstrated to produce host tissue damage in animal models of autoimmune diseases such as collagen-induced arthritis, myasthenia gravis, and membranous nephropathy. Complement activation also, in part, mediates the tissue destruction which occurs following myocardial infarction and burn injuries. There exists a need for the identification of substances that are effective in inhibiting or suppressing complement-mediated immune responses. See column 1, line 54, through column 2, line 5. Krumdieck also teaches that the proteoglycan decorin has the ability to bind to C1q and suppress or inhibit C1 complex biological activity. In

¹Citations by the examiner are in an alphanumeric format, such as "(a1)", wherein the "a" refers to the reference cited on the Notice of References Cited, PTO-892, and the "1" refers to the Paper No. to which the Notice of References Cited, PTO-892, is attached.

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diseases where complement is misdirected or excessively activated resulting in damage to host tissues, it is proposed that this inhibition will suppress one or more of the deleterious effects of antibody-mediated complement activation, such as recruitment and activation of inflammatory cells, vasodilation, and/or direct cell killing via formation of membrane attack complex which is

5 the lytic component system, thereby providing significant advantages over existing therapies and an ideal solution to the problem of complement activation. See column 2, lines 25-38.

Krumdieck does not teach a method of treatment of the human or animal body comprising the use of a cC1qR binding domain.

Stuart (1996, cited by Applicants) Stuart teaches that the C1q binding site of C1qR is 10 localized on the S-domain and that strong C1q inhibitory activity is localized to the S-domain (paragraph bridging pages 248-249). Stuart teaches that the S-domain comprises amino acid residues 160-283 (Table 1). Stuart teaches that the C1qR is almost identical to calreticulin (page 245, first paragraph of Introduction). Stuart does not teach a method of treatment of the human or animal body comprising the use of a cC1qR binding domain.

15 However, it would have been obvious to one of ordinary skill in the art at the time of Applicants' invention to bind C1q and suppress or inhibit C1 complex biological activity, as taught by Krumdieck, and to modify that teaching by binding C1q with the S-domain of C1qR and strongly inhibit C1q activity, as taught by Stuart, with a reasonable expectation of success. One of ordinary skill in the art would be motivated to combine these teachings in order to minimize

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damage to host tissues as a result of misdirection or excessive activation of complement. The invention is *prima facie* obvious over the prior art.

Claim Rejections - 35 USC § 112, 101

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

5 The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. 35 U.S.C. 101 reads as follows:

10 Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

10. Claim 10 provides for the use of a cC1qR binding domain, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

15 Claim 10 is rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

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Conclusion

11. Claim 10 is not allowable.

12. The prior art made of record and not relied upon is considered pertinent to applicant's

disclosure. Mazzarella (u9) teaches the amino acid sequences of human and mouse

5 ERp60/calregulin (Figure 6) which have the amino acid sequence of SEQ ID NO: 1 and 3,
respectively.

AP 6/11/1

13. A claim limited to SEQ ID NO: 2 appears to be free of the prior of record and allowable.

10 ANY INQUIRY CONCERNING THIS COMMUNICATION OR EARLIER COMMUNICATIONS FROM THE EXAMINER
SHOULD BE DIRECTED TO DAVID S. ROMEO WHOSE TELEPHONE NUMBER IS (703) 305-4050. THE EXAMINER CAN
NORMALLY BE REACHED ON MONDAY THROUGH FRIDAY FROM 6:45 A.M. TO 3:15 P.M.

IF ATTEMPTS TO REACH THE EXAMINER BY TELEPHONE ARE UNSUCCESSFUL, THE EXAMINER'S SUPERVISOR,
GARY KUNZ, CAN BE REACHED ON (703) 308-4623.

OFFICIAL PAPERS FILED BY FAX SHOULD BE DIRECTED TO (703) 308-4242.

15 FAXED DRAFT OR INFORMAL COMMUNICATIONS SHOULD BE DIRECTED TO THE EXAMINER AT (703) 308-0294.

ANY INQUIRY OF A GENERAL NATURE OR RELATING TO THE STATUS OF THIS APPLICATION OR PROCEEDING
SHOULD BE DIRECTED TO THE GROUP RECEPTIONIST WHOSE TELEPHONE NUMBER IS (703) 308-0196.

David Romeo
DAVID ROMEO
PRIMARY EXAMINER
ART UNIT 1647

20 JUNE 11, 2001